II. REMARKS

Reconsideration of the present application as amended, and in view of the following remarks, is respectfully requested.

Claims 1-16 and 20-38 and 40-45 are currently pending. Claim 44 has been amended without prejudice. Claim 39 has been previously withdrawn. Claims 17-19 have been previously canceled. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

A. REJECTION UNDER 35 U.S.C. § 112

Claim 35 was rejected under 35 U.S.C. §112, second paragraph, on the grounds that the term "rubber-like polymer" does not set out the meets and bounds of the claim.

In response, it is respectfully submitted that the meets and bounds of the term, "rubber-like synthetic polymer" is known by those of skill in the art. This is evidenced by, e.g. U.S. Patent 5,240,711 to Hille et al. (cited in the present Office Action) which states at column 3, line 25, "[e]xamples of polymers are rubber, rubber-like synthetic homo-, co- or blockpolymers, polyacrylic esters and copolymers thereof, polyurethanes and silicones."

Claim 44 was rejected on the grounds that the limitation, "softening ester" lacks sufficient antecedent basis in claim 23. In response, claim 44 has been amended without prejudice to recite "softening agent" in place of "softening ester" in order to be in proper antecedent form.

In view of the actions taken and arguments made, the Examiner is respectfully requested to remove the rejections under 35 U.S.C. §112, second paragraph.

B. REJECTION UNDER 35 U.S.C. § 103

Claims 1-16, 20-38 and 40-45 were rejected under 35 U.S.C. § 103(a), "as being unpatentable over WO 93/10781 (hereafter, "WO'781") in view of U.S. Patent No. 5,091,186 to Miranda et al. (hereafter, "Miranda et al."). Applicant respectfully traverses this rejection.

The Office Action acknowledges that WO'781 "does not teach the specific delivery profile claimed by the applicant ... " The Office Action further contends that "it would have been obvious to one having ordinary skill in the art at the time of the invention to treat hypertension and angina using a transdermal device comprising felodipine, as disclosed by WO'781, and provide the felodipine in the transdermal delivery device disclosed by Miranda et al. that provide a particular delivery profile, motivated by the teaching of Miranda et al. that a given drug loading value will provide a certain duration of delivery rate depending on the drug loading, with reasonable expectation of having a transdermal drug delivery device to deliver felodipine to treat hypertension and angina effectively."

The Examiner is directed to independent method claims 1 and 8, which recite, in part, the following:

Claim 1: A method ... comprising ... maintaining said transdermal delivery system in contact with the skin of said patient **for at least three days** ... and thereafter maintaining a therapeutic blood level until the end of **at least the three day dosing interval**. (Emphasis Added)

Claim 8: A method ... comprising ... maintaining said transdermal delivery system in contact with the skin of said patient **for at least five days** ... and thereafter maintaining a therapeutic blood level until the end of **at least the five day dosing interval**. (Emphasis Added)

The Office Action acknowledges that WO'781 does not teach the delivery profile of claims 1 and 8 and relies on Miranda et al. to cure the deficiencies of WO'781 publication.

However, Miranda et al. teach at column 6, lines 20-21, that the system described therein "enables biphasic delivery **over an approximately 24-hour dosing period** ..." (Emphasis Added). Miranda et al. further describe at column 7, lines 37-39, that "[t]he patch may thus be removed and replaced **every day** at about the same time." (Emphasis Added). Applicant contends that Miranda et al. neither teach nor suggest maintaining the transdermal delivery system in contact with the skin of the patient for at least 3 or 5 days, as claimed in claims 1 and 8 respectively, nor teach or suggest maintaining a therapeutic blood level until the end of at least the 3 or 5 day dosing interval, as additionally claimed in claims 1 and 8 respectively. Applicant respectively contends that Miranda et al. do not provide any indication that the device described therein is suitable for at least a 3 or 5 day dosing interval, nor does it provide the motivation to attempt to achieve such a result as alleged in the Office Action.

Therefore, even if one modifies WO'781 with Miranda et al. as alleged in the Office Action, a modification Applicant respectfully contends Miranda et al. provides no motivation to do, the resulting felodipine transdermal system would at best be suitable for 24 hours. The Office Action fails to provide how one of ordinary skill in the art would be motivated to modify the transdermal delivery system of WO'781 with Miranda et al. to achieve a therapeutic blood level for at least a 3 or 5 day dosing interval as recited in claims 1 and 8 respectively.

The Examiner is also directed to independent claim 20 which includes a transdermal delivery system having in part:

(i) a plasma level of felodipine of at least about 0.1 ng/ml by about 6 hours, and

(ii) a plasma level of felodipine at steady-state from about 0.1 to about 3.3 ng/ml.

With respect to the claimed felodipine plasma levels, Applicant respectfully submits that Miranda et al. cannot cure the deficiencies of WO'781 because there is no teaching in Miranda et al. of a felodipine transdermal delivery system . Therefore, the felodipine plasma levels claimed in independent claim 20 (as well as dependent claims 2-4, 11-13, and 27-29) are neither taught nor suggested by Miranda et al. Accordingly, one skilled in the art would not arrive at the invention as claimed in claim 20 based on modifying WO'781 with Miranda et al. as alleged in the Office Action.

The Examiner is also directed to independent composition claim 26 which recites, in part, ". . . maintaining a therapeutic blood level ***until the end of at least the five-day dosing interval***." Applicant respectfully submits that claim 26 is neither taught nor suggested by WO'781 in view of Miranda et al. according the arguments presented above with respect to claim 8.

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO'781 in view of Miranda et al. as applied to claims 1-16, 20-38 and 40-45 above, and further in view of U.S. Patent No. 5,240,711 (hereafter " Hille"), based upon Hille's purported teaching of solvents and softening agents. Applicant respectfully traverses this rejection.

Hille is directed to a buprenorphine transdermal delivery device. Hille neither teaches nor suggests a transdermal delivery device utilizing any active agent other than buprenorphine. Accordingly, Applicant contends one skilled in the art would not be motivated to combine Hille with the WO'781 in order to produce a felodipine transdermal delivery system that delivers plasma levels of felodipine as claimed in independent claim 20, and in dependent claims 37, 38, 44 and 45. Therefore, even assuming arguendo that cited prior art were combined in the matter proposed in the Office Action, one skilled in the art would still not arrive at the invention as claimed in claims 37, 38, 44 and 45.

III. CONCLUSION

Applicant believes that the above-referenced rejections have been obviated and respectfully request that the rejections be withdrawn. Applicant believes that all claims are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,
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